Statement of J. David Erickson at the FDA public meeting on safety issues associated with dietary supplement use during pregnancy. Gaithersburg, MD, March 30, 2000

Good afternoon. I'm Dave Erickson, Chief of the Birth Defects and Genetic Diseases Branch at CDC. I am grateful for the opportunity to be here today to talk with you about our concern about the possible harm that might result from promotion of certain types of dietary supplements for use during pregnancy.

Our group at CDC uses epidemiologic research to increase knowledge about why birth defects occur. When modifiable causes are found, we promote prevention. Thus, we are keen promoters of increased consumption of folic acid before conception and during early pregnancy for the prevention of neural tube defects. And so it will not be surprising that we promote the use of dietary supplements containing folic acid by women before and during early pregnancy.

It is well known that substances that are innocuous to adults have the potential to cause substantial embryonic and fetal damage. Rubella is often only a mild illness in pregnant women, but it can cause devastating problems to the developing baby. Thalidomide was widely prescribed as a safe and effective treatment for the nausea of early

pregnancy. You all know how wrong the assumption of safety was, and how use of thalidomide by women during early pregnancy led to an epidemic of limb deformities among babies born in Europe 40 years ago. Thus we feel that there is a real cause for concern that fetal damage may be done by promoting the use of seemingly innocuous dietary supplements among women who are pregnant.

I see no contradiction in our advocacy for increased folic acid intake through consumption of supplements, and our generic concern that unregulated promotion of dietary supplements for use by pregnant women might be dangerous. To me the crucial difference is that folic acid use during early pregnancy has been studied extensively in high quality scientific studies, including randomized trials. It has been found to be efficacious in preventing a large fraction of some types of very serious defects. And in the same studies it has been found to be safe for fetuses. Babies whose mothers use folic acid-containing supplements have a better chance of being born healthy than babies whose mothers do not use folic acid-containing supplements.

The first question FDA asks of participants in this hearing is related to the potential hazards of the use of

supplements by pregnant women and fetuses, and whether these hazards should be considered different than potential hazards to other classes of users.

It is undeniable that pregnancy is a natural, essential, normal part of the human life cycle. Perhaps this was the rationale for FDA specifically mentioning two common complications of pregnancy, morning sickness and mild edema, as potential candidates for supplement labeling under the so-called "structure\function" rule. However, it is as undeniable that pregnancy is a very special and potentially vulnerable stage of life. The pregnant woman is potentially vulnerable, of course. But there is an additional and unique concern for the developing child. This concern is most acute during early pregnancy, when the critical processes of organogenesis are taking place, and when women have to deal with problems like morning sickness. Because of this concern about a special potential vulnerability, I believe that the standards that govern the labeling of supplements relative to use by pregnant women should be more stringent than the standards that govern the use of supplement labeling for non-pregnant adults. I think that permission for labeling a supplement as being helpful during pregnancy should be held to not

less than the standard that was set for allowing health claims to be made for folic acid supplements for neural tube defect risk reduction. Even better in my opinion would be to hold supplement labeling to the same standard as are drugs.

I surmise that FDA is asking how, under the Dietary Supplement Health and Education Act, it can acknowledge the special situation that is pregnancy, this special time of life with special vulnerabilities. I am not a lawyer or regulator. I have no personal expertise or experience that would allow me to give legal or regulatory advice to FDA. All that I can offer is “common sense.” To me, allowing the labeling of a supplement as being good for alleviating common and unpleasant complications of pregnancy carries to the potential consumer an implicit message of safety for the fetus.

My idea of “common sense” in this matter is that if a woman is pregnant, and desires to continue her pregnancy, she wants a healthy baby. And if she thinks that a supplement is presented as being helpful to her as a pregnant woman, it is being presented as being OK for her baby as well.

As I understand it, the Dietary Supplement Health and Education Act requires truthfulness in labeling. And it requires some sort of substantiation of the message being conveyed by the label. If a recommendation for use of something during pregnancy carries with it an implicit message of safety for the fetus, and if there is no substantiation of that safety, then I contend that the label would be untruthful. In my non-legalistic view, the product would be mislabeled. With this point of view, I think a case can be made that a label that conveys an implicit message of safety for the fetus should be backed up by an explicit substantiation of safety for the fetus.

To my way of thinking, there is no condition connected with pregnancy for which structure/function label claims should be allowed, unless there is a substantiation of safety for the fetus. As I have said before, if a supplement is to be labeled for use by pregnant women, it should at minimum meet the standard for a supplement health claim, or better yet, the standard for a drug. By saying this, I am not advocating that pregnancy be called a “disease.” I am merely saying that the standard of evidence substantiating safety should be high.

I think that in what I have already said, I have essentially answered the questions FDA posed for this hearing, except the one about whether supplement labels should contain a caution against any supplement use by pregnant women. Like Dr Kendrick before me, I think that this would be a judicious approach, except in the case where the supplement in question has met the standard for a health claim or a drug, as is the case for folic acid.

Thank you for your attention. I have appreciated the opportunity to talk with you about this very important topic.